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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/608,354	06/27/2003	Stanley T. Crook	MSIBIS-0002USC2	2899
27180	7590	11/17/2006		
ISIS PHARMACEUTICALS INC 1896 RUTHERFORD RD. CARLSBAD, CA 92008			EXAMINER LU, FRANK WEI MIN	
			ART UNIT	PAPER NUMBER
			1634	

DATE MAILED: 11/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/608,354

Applicant(s)

CROOK ET AL.

Examiner

Frank W. Lu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 9/5/2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 36-47 and 95-108 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 36-47 and 95-108 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 1/2005.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group IV (claims 36-48) in the reply filed on September 5, 2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Since claims 40 and 48 have been canceled and new claims 95-108 have been added, claims 36-39, 41-47, and 95-108 will be examined.

Information Disclosure Statement

2. Some references in information disclosure statement filed on January 18, 2005 (see sheets 11 and 12) are books. Since applicant did not submit these book in cases in 09/884,317, 09/260,310, 09/076,206, and this instant applicant, these references have not been considered.

Specification

3. The disclosure is objected to because of the following informalities: (1) since U.S. Patent Application Serial No. 09/076,206 now is US Patent No. 6,428,956, applicant is required to update this information in the first sentence of the specification; and (2) there are several nucleotide sequences with more than 10 nucleotides in Figures 1, 4, 5, 7-12, 24, and 27. However, there are no SEQ ID Nos for these nucleotide sequences in Figures 1, 4, 5, 7-12, 24, and 27 and there is no description for these nucleotide sequences in BRIEF DESCRIPTION OF THE DRAWINGS of the specification.

Appropriate correction is required.

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Claim Objections

4. Claim 42 is objected to because of the following informality: "step {circle over (c)}" should be "step (c)".

Appropriate correction is required.

Double Patenting

5. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

6. Claims 36-41 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 27-32 of prior U.S. Patent No. 6,656,690 B2. This is a double patenting rejection.

7. Claims 42-47 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 10-15 of prior U.S. Patent No. 6,329,146 B1. This is a double patenting rejection.

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection

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is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 95-104 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 27-32 of prior U.S. Patent No. 6,656,690 B2. Since the compound recited in claim 27 of U.S. Patent No. 6,656,690 B2 can be an oligonucleotide or a small molecule (see U.S. Patent No. 6,656,690 B2, column 22, last paragraph bridging to page 23, first paragraph), claim 27 of U.S. Patent No. 6,656,690 B2 disclose claims 95 and 97 of this instant application. Since RNA recited in claim 29 of U.S. Patent No. 6,656,690 B2 comprises mismatched base pair, loop, bulge, kink, or stem structure (see U.S. Patent No. 6,656,690 B2, column 5, last paragraph bridging to page 6, first paragraph) and highly conserved molecular interaction sites among taxonomically diverse species (see U.S. Patent No. 6,656,690 B2, column 26, lines 28-41), claim 38 of U.S. Patent No. 6,656,690 B2 discloses claims 96 and 98

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this instant application. Since claims 99-104 are identical to claims 37, 38, and 95-98 are identical to claims 99-104, claims 27-32 of U.S. Patent No. 6,656,690 B2 disclose claims 99-104 of this instant application.

10. Claims 105-108 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 10-15 of prior U.S. Patent No. 6,329,146 B1. Since the compounds recited in claim 10 of U.S. Patent No. 6,329,146 B1 can be oligonucleotides or small molecules (see U.S. Patent No. 6,329,146 B1, column 22, last paragraph bridging to page 23, first paragraph), claim 10 of U.S. Patent No. 6,329,146 B1 disclose claims 105 and 108 of this instant application. Since RNA recited in claim 13 of U.S. Patent No. 6,329,146 B1 comprises mismatched base pair, loop, bulge, kink, or stem structure (see U.S. Patent No. 6,329,146 B1, column 5, last paragraph bridging to page 6, first paragraph) and highly conserved molecular interaction sites among taxonomically diverse species (see U.S. Patent No. 6,329,146 B1, column 26, lines 28-41), claim 13 of U.S. Patent No. 6,656,690 B2 discloses claims 106 and 107 of this instant application.

Conclusion

11 No claim is allowed.

12 Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30

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(November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is (571)273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (571)272-0746.

The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on (571)272-0735.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

November 9, 2006



FRANK LU
PRIMARY EXAMINER